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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,084	10/24/2001	Avi J. Ashkenazi	GNE.2630P1C66	4358

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HELLER EHRMAN WHITE & MCAULIFFE LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CO 94025-3506

EXAMINER

BLANCHARD, DAVID J

ART UNIT PAPER NUMBER

1642

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,084

Applicant(s)

ASHKENAZI ET AL.

Examiner

David J Blanchard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-65, 68-70 and 74-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 63-70 is/are allowed.
- 6) ☒ Claim(s) 58-62 and 74-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 58-63 have been amended.
Claims 66-67 and 71-73 have been canceled.
2. Claims 58-65, 68-70 and 74-77 are pending and under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. This Office Action contains New Grounds of Rejections.

Priority

5. The examiner acknowledges the preliminary amendment updating the priority statement on the first line of the specification was filed on 10/24/2003 and has been entered in full. The examiner acknowledges the same filed 3/11/2004.

Withdrawn Objections And/or Rejections

6. The objection to the specification for containing the old ATCC address is withdrawn in view of the amendment filed 3/11/2004, providing the updated ATCC address.
7. The objection to the specification for containing embedded hyperlinks is withdrawn in view of the amendments to the specification filed 3/11/2004.
8. The rejection of claims 58-77 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention is withdrawn in view of the amendments to the claims and the cancellation of claims 66-67 and 71-73.

9. The rejection of claims 71-73 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the cancellation of claims 71-73.

10. The rejection of claims 58-62 under 35 U.S.C. 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims and Applicant's arguments.

11. The rejection of claims 58-62, 70-77 under 35 U.S.C. 112, first paragraph, enablement, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in view of the successful completion of the deposit requirements and the cancellation of claims 71-73.

12. The rejection of claims 58-62 and 71-77 under 35 U.S.C. 112, first paragraph, enablement, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in view of the amendments to the claims and the cancellation of claims 71-73.

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13. The rejection of claims 71-73 under 35 U.S.C. 102(b) as being anticipated by over Struyk et al is withdrawn in view of the cancellation of claims 71-73.

14. The rejection of claims 71-72 under 35 U.S.C. 102(b) as being anticipated by over The 1991 Boehringer Mannheim Catalog is withdrawn in view of the cancellation of claims 71-72.

New Grounds of Rejections

15. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 76, as written, does not sufficiently distinguish over cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. The specification contemplates viral vectors and eukaryotic host cells (see pages 186-187), which broadly reads on animal and human host organisms having a retroviral infection as they exist in nature. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

16. Claims 58-62 and 74-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 58-62 and 71-74 are indefinite for reciting "wherein the nucleic acid encodes a polypeptide that is a mitogen for inner ear supporting cells" in claims 58-62 because it is unclear which nucleic acid the phrase refers to. Does the phrase "wherein the nucleic acid encodes a polypeptide that is a mitogen for inner ear supporting cells" mean that the nucleic acids having at least 80-99% nucleic acid sequence identity encode polypeptides that are mitogens for inner ear supporting cells or does the phrase mean that the nucleic acid of (a) or (b) or (c) or (d) or (e), or all of (a) through (e) or do all of the nucleic acids recited in claims 58-62 encode polypeptides that are mitogens for inner ear supporting cells? As written, the meets and bounds of the claims cannot be determined.

b. Claims 58-62, recite the limitation "the nucleic acid" on the last line of the claims. There is insufficient antecedent basis for this limitation in the claims. Additionally, Part (e) of the claims does not recite any "nucleic acid".

17. Claims 58 and 74-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Struyk et al (The Journal of Neuroscience, 15(3):2141-2156, March 1995) as evidenced by Gil et al (Journal of Neurobiology, 51:190-204, 2002).

The claims are drawn to isolated nucleic acids having at least 80% identity to nucleic acid sequences encoding SEQ ID NO:523, lacking its associated signal peptide, the full-length coding sequence of the nucleic acid sequence of SEQ ID NO:522 and the full-length coding sequence deposited as ATCC accession no. 209487, wherein all of the above nucleic acid sequences are interpreted to encode a polypeptide that is a

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mitogen for inner ear supporting cells. The claims are also drawn to a vector comprising the nucleic acids and a host cell comprising said vector, wherein the host cell is a CHO cell, an E.coli or a yeast cell.

Struyk et al teach a polynucleotide sequence having at least 80% identity with a nucleic acid sequence encoding the polypeptide of SEQ ID NO:523, lacking its associated signal peptide, the full-length coding sequence of SEQ ID NO:522, and the full-length coding sequence of the cDNA deposited under ATCC accession number 209487 (see Figure 3 and the alignment attached to the back of this Office Action). Struyk et al teach that the polynucleotide was isolated from a Stratgene P5 rat brain library and plasmid rescue was carried out by excision with R408 helper phage (see page 2142, right column). Thus, Struyk et al teach a vector (i.e., plasmid) comprising a polynucleotide having at least 80% identity encoding the polypeptide of SEQ ID NO:523, lacking its associated signal peptide, the full-length coding sequence of SEQ ID NO:522, and the full-length coding sequence of the cDNA deposited under ATCC accession number 209487 as well as host cells comprising said vector. Struyk et al also teach that the polynucleotide having at least 80% identity with the coding sequence of SEQ ID NO:522 encodes a rat neurotrimin polypeptide having 97% identity with the polypeptide of SEQ ID NO:523, lacking its associated signal peptide (i.e., full-length coding sequence) (see Figure 3 and the sequence attached to the back of this Office action; residues 29-344 of SEQ ID NO:523) and neurotrimin is a member of the immunoglobulin gene superfamily (IgSF) of glycosylphosphatidylinositol (GPI) anchored cell adhesion molecules (see page 2141, right column and abstract). Further, Struyk et

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al teach that the cell adhesion molecules of the IgSF constitute a large family of proteins implicated in neural cell interactions and nerve fiber outgrowth during development (see bridging paragraph of pages 1214-1242). The instant specification discloses that the polynucleotide of SEQ ID NO:522, which encodes SEQ ID NO:523 (i.e., PRO337) is a newly identified member of the IgLON subfamily of the immunoglobulin superfamily and may possess neurite growth and differentiation potentiating properties (see page 179, lines 36-37). As evidenced by Gil et al (Journal of Neurobiology, 51:190-204, 2002) neurotrimin is a member of the IgLON family of GPI-anchored neural cell adhesion molecules (see abstract). Therefore, it is the Examiner's position that Struyk et al have produced a polynucleotide, which encodes a polypeptide that is a mitogen for inner ear supporting cells. One of ordinary skill in the art would reasonably conclude that the neurotrimin polypeptide of Struyk et al also possesses the same functional properties as those of the encoded polypeptides of SEQ ID NO:523 claimed and, therefore, it appears that Struyk et al has produced a polynucleotide that encodes a polypeptide that is functionally identical to the encoded polypeptides of SEQ ID NO:523 claimed. Since the Patent and Trademark Office does not have the facilities for examining and comparing the encoded polypeptides of SEQ ID NO:523 claimed with the polypeptide of Struyk et al, the burden of proof is upon the Applicants to show an unobvious distinction between the functional characteristics of the claimed encoded polypeptides of SEQ ID NO:523 and the encoded polypeptide of the prior art. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

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Conclusions

18. Claims 63-65 and 68-70 are in condition for allowance. The prior art does not teach or fairly suggest the isolated nucleic acids encoding SEQ ID NO:523 or the nucleic acid of SEQ ID NO:522.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at (571) 272-0827 from 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841.

Official papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The official fax number for Group 1600 where this application or proceeding is assigned is (703) 872-9306.

Respectfully,
David J. Blanchard
571-272-0827



LARRY R. HELMS, PH.D
PRIMARY EXAMINER